4. Section 1310.14 is proposed to be amended by revising the heading and by revising paragraph (a) to read as follows:

§ 1310.14 Exemption of certain ephedrine or pseudoephedrine combination drug products.

(a) Any manufacturer of a drug product containing ephedrine in combination with another active medicinal ingredient, the product formulation of which is not listed in the compendiums set forth in Section 1310.01(f)(1)(iv)(A)(1), or any manufacturer of a drug product containing pseudoephedrine in combination with acetaminophen, aspirin or ibuprofen, the product formulation of which is not listed in the compendiums set forth in Section 1310.01(f)(1)(iv)(A)(2), may request that the Administrator exempt the product as one which contains ephedrine together with therapeutically significant quantities of the other active medicinal ingredients or pseudoephedrine in combination with therapeutically significant quantities of acetaminophen, aspirin or ibuprofen.

* * * * *

5. Section 1310.15 is proposed to be amended by revising the heading, by revising paragraph (a), and by revising paragraph (d) to read as follows:

§ 1310.15 Exempt combination drug products containing ephedrine or pseudoephedrine.

(a) The drug products containing ephedrine in combination with therapeutically significant quantities of another active medicinal ingredient, or pseudoephedrine in combination with therapeutically significant quantities of acetaminophen, aspirin, or ibuprofen; listed in paragraph (e) of this section, have been exempted by the Administrator from application of sections 302, 303, 310, 1007, and 1008 of the Act (21 U.S.C. 822–3, 830, and 957–8) to the extent described in paragraphs (b), (c), and (d) of this section.

* * * * *

(d) In addition to the drug products listed in the compendium set forth in Section 1310.01(f)(1)(iv)(A)(1) and 1310.01(f)(1)(iv)(A)(2), the following drug products, in the form and quantity listed in the application submitted (indicated as the ''date'') are designated as exempt drug products for the purposes set forth in this section:

EXEMPT DRUG PRODUCTS CONTAINING EPHEDRINE IN COMBINATION WITH THERAPEUTICALLY SIGNIFICANT QUANTITIES OF ANOTHER ACTIVE MEDICINAL INGREDIENT AND EXEMPT DRUG PRODUCTS CONTAINING PSEUDOEPHEDRINE IN COMBINATION WITH THERAPEUTICALLY SIGNIFICANT QUANTITIES OF ACETAMINOPHEN, ASPIRIN OR IBUPROFEN

Supplier	Product name	Form	Date
[Reserved]	.....	.....	.....

PART 1313—[AMENDED]

1. The authority citation for Part 1313 continues to read as follows:

Authority: 21 U.S.C. 802, 830, 871(b), 971.

2. Section 1313.02 is proposed to be amended by revising paragraph (d)(1)(iv)(A) to read as follows:

§ 1313.02 Definitions.

* * * * *

(d) * * *

(1) * * *

(iv) * * *

(A)(*1*) The drug contains ephedrine or its salts, optical isomers, or salts of optical isomers as the only active medicinal ingredient or contains ephedrine or its salts, optical isomers, or salts of optical isomers and therapeutically insignificant quantities of another active medicinal ingredient. For purposes of this paragraph, the term ''therapeutically insignificant quantities'' shall apply if the product formulation (i.e. the qualitative and quantitative composition of active ingredients within the product) is not listed in current editions of the American Pharmaceutical Association (APhA) Handbook of NonPrescription Drugs; Drug Facts and Comparisons (published by Wolters Kluwer Company); or USP DI (published by the authority of the United States Pharmacopeial Convention, Inc.); or the product is not listed in Section 1310.15 as an exempt drug product. For drug products having formulations not found in the above compendiums, the Administrator shall determine, pursuant to a written request as specified in Section 1310.14, whether the active medicinal ingredients are present in quantities considered therapeutically significant for purposes of this paragraph; or

(*2*) The drug is an over-the-counter (OTC) solid dosage form product (tablet, capsule or powder packet) which contains pseudoephedrine or its salts, optical isomers, or salts of optical isomers, but does not contain either acetaminophen, aspirin or ibuprofen in therapeutically significant quantities. For purposes of this paragraph, the quantities of either acetaminophen, aspirin or ibuprofen present in a pseudoephedrine drug product shall be considered to be present in ''therapeutically significant quantities'' if the product formulation (i.e. the qualitative and quantitative composition of the active ingredients within the product) is listed in current editions of the American Pharmaceutical Association (APhA) Handbook of NonPrescription Drugs; Drug Facts and Comparisons (published by Wolters Kluwer Company); or USP DI (published by the authority of the United States Pharmacopeial Convention, Inc.); or the product is listed in Section 1310.15 as an exempt drug product. For drug products having a formulation not found in the above compendiums, the Administrator shall determine, pursuant to a written request as specified in Section 1310.14, whether the active medicinal ingredients (acetaminophen, aspirin or ibuprofen) are present in quantities considered therapeutically significant for purposes of this paragraph; or

* * * * *

Dated: October 25, 1995.

Stephen H. Greene,

Deputy Administrator.

[FR Doc. 95–26890 Filed 10–30–95; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF LABOR

Mine Safety and Health Administration

30 CFR Parts 14, 18, and 75

RIN 1219–AA92

Requirements for Approval of Flame-Resistant Conveyor Belts

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Proposed rule; reopening of the record; request for public comment.

SUMMARY: The Mine Safety and Health Administration (MSHA) is reopening the rulemaking record to receive additional test data, technical information, and further comment on proposed revisions to its regulations for the approval of flame-resistant conveyor belts for use in underground coal mines. After the close of the public record, some commenters indicated to MSHA that they had obtained or would be obtaining flame test data and technical

information which MSHA should review and evaluate. This new information is relevant to MSHA's proposed rule and the Agency's technical assessment of other flammability test data. Also, MSHA has placed the Agency's response to questions from certain commenters in the rulemaking record for public review.

DATES: Written material and comments must be submitted by December 15, 1995.

ADDRESSES: Send written comments to MSHA; Office of Standards, Regulations, and Variances; 4015 Wilson Boulevard, Room 631; Arlington, VA 22203. Commenters are encouraged to submit comments on a computer disk along with a hard copy.

FOR FURTHER INFORMATION CONTACT: Patricia W. Silvey, Director; Office of Standards, Regulations, and Variances; 703–235–1910.

SUPPLEMENTARY INFORMATION:

I. Background

On December 24, 1992, MSHA published a proposed rule (57 FR 61524) to implement new procedures and requirements for testing and approval of flame-resistant conveyor belts and requirements for their use in underground coal mines. The proposed revision would replace the existing flame test for acceptance of flame-resistant belts specified in Agency regulations. The comment period on the proposed rule closed on March 26, 1993. Several commenters requested that the Agency hold a public hearing on its proposal. The comment period on the proposed rule was reopened until April 21, 1995, and on May 2, 1995, MSHA held a public hearing in Washington, PA (60 FR 16589, March 31, 1995). The post-hearing comment period closed on June 5, 1995.

II. Issues

Following the close of the post-hearing comment period, a manufacturer indicated that additional flammability testing of conveyor belts was scheduled using the Factory Mutual conveyor belt flammability test (FM test) and invited MSHA to witness that testing. To avoid participation in testing where all parties to the rulemaking were not invited, and because the record was closed, MSHA neither witnessed these tests nor received the results of this testing. Another manufacturer also requested that MSHA accept additional flammability test data generated from the FM test that were not available during the comment period.

Also, in the comments submitted during the post hearing comment period, the United Mine Workers of America (UMWA) and the Bituminous Coal Operators' Association (BCOA) jointly submitted 10 questions to MSHA. MSHA's response is being placed in the rulemaking record and is available to the public from MSHA, Office of Standards, Regulations, and Variances.

MSHA is reopening the record for 45 days to provide all interested parties an opportunity to review the record and to submit additional data, test results, and technical information. MSHA encourages all interested parties to submit comments prior to the close of the record.

Dated: October 18, 1995.

J. Davitt McAteer,

Assistant Secretary for Mine Safety and Health.

[FR Doc. 95–26373 Filed 10–24–95; 8:45 am]

BILLING CODE 4510–43–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[FRL–5296–6]

Approval and Promulgation of Implementation Plans and Designation of Areas for Air Quality Planning Purposes; State of Connecticut

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The EPA proposes to approve the State Implementation Plan (SIP) revision submitted by the State of Connecticut to redesignate the Hartford/New Britain/Middletown area from nonattainment to attainment for carbon monoxide (CO). Under the Clean Air Act as amended in 1990 (CAA), designations can be revised if sufficient data is available to warrant such revisions.

In addition, EPA is approving two related State Implementation Plan (SIP) submissions by Connecticut DEP. On January 12, 1993, Connecticut DEP submitted a final 1990 base year emission inventory for CO emissions, which includes emissions data for all sources of CO in Connecticut's two CO nonattainment areas (the Hartford/New Britain/Middletown area and the Connecticut portion of the New York/New Jersey/Connecticut Consolidated Metropolitan Statistical Area (CMSA). On January 12, 1993, January 14, 1993, September 30, 1994 and August 1, 1995, Connecticut DEP submitted an oxygenated fuel program and revisions for both CO nonattainment areas.

In the Final Rules Section of this Federal Register, EPA is approving the CO emissions inventory for both areas and the oxygenated fuels program only as it applies to the Hartford/New Britain/Middletown nonattainment area as a direct final rule. In addition, EPA is also approving Connecticut's redesignation, as a direct final rule without prior proposal. A detailed rationale for the action is set forth in the direct final rule. If no adverse comments are received in response to that direct final rule, no further activity is contemplated in relation to this proposed rule. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period on this document. Any parties interested in commenting on this document should do so at this time.

DATES: Comments must be submitted by November 30, 1995.

ADDRESSES: Written comments should be sent to Damien Houlihan, at the EPA Regional Office listed below. Copies of the redesignation request and the State of Connecticut's submittal are available for public review during normal business hours at the addresses listed below.

Air and Radiation Docket and Information Center, U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460, and; Environmental Protection Agency, One Congress Street, Boston, MA 02203.

FOR FURTHER INFORMATION CONTACT: Damien Houlihan of the EPA Region I Air, Pesticides and Toxics Management Division at (617) 565–3266.

Dated: August 31, 1995.

John P. DeVillars,

Regional Administrator, Region I.

[FR Doc. 95–26962 Filed 10–30–95; 8:45 am]

BILLING CODE 6560–50–P

40 CFR Part 52

[CA 162–1–7250b; FRL–5321–2]

Approval and Promulgation of State Implementation Plans; California State Implementation Plan Revision, South Coast Air Quality Management District and Santa Barbara County Air Pollution Control District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.